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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/946,236 09/15/92 JACOBS

2503

EXAMINER

NISE 1,1

18M2/0/27

LEGAL AFFAIRS DEPARTMENT
IMMUNEX CORPORATION
31 UNIVERSITY STREET
SEATTLE, WA 98101

ART UNIT

PAPER NUMBER

1806

DATE MAILED:

07/27/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

- ☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.
FOR RESTRICTION PURPOSES ONLY
A shortened statutory period for response to this action is set to expire 30 months, 30 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-9 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☐ Claims _____ are rejected.
5. ☐ Claims _____ are objected to.
6. ☒ Claims 1-9 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable, ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

III. RESTRICTION REQUIREMENT

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-6 and 8-9, drawn to methods of treating arthritis via the use of TNF receptor proteins, classified in Class 424, subclass 85.1.

II. Claim 7, drawn to a combination therapy using both IL1 receptor antagonists and TNF receptor antagonists, classified in Class 424, subclass 85.1.

The inventions are distinct, each from the other because of the following reasons:

The use of the two receptor antagonist versus the use of a single receptor antagonist is considered to be the consideration of two separate methods of use. The distinctness of the methods is based on the products used in the methods. In the method of Group I, the TNF receptors are used alone while in Group II, the IL1 receptor is used in combination. The addition of the IL1 receptor affects the method itself. It has been shown that the administration of two cytokines together often results in a synergistic effect on the target disease or cell line. The consideration of any synergistic effects represents a separate issue from the administration of TNF receptors alone. Moreover, the search for therapies with IL1 would require separate searches which represents a burden to the examiner. Finally, the structure of the IL1r protein as represented by its' amino acid sequence is distinct from that of TNFr protein. Accordingly, a method of therapy performed with TNFr would not be predictable with IL1r. Therefore, because of the separate etiology represented by the synergy present with two cytokines, the separate search required for IL1, and the unpredictability based on the separate structure, restriction is deemed necessary.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art based on their recognized divergent subject matter and their separate search, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition

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under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

5 A telephone call was made to Kevin Malaska on 7/25/93 to request an oral election to the above restriction requirement, but did not result in an election being made.

10 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Nisbet whose telephone number is (703) 308-4204. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

15 TMN
July 26, 1993

Christina Chan
Y. CHRISTINA CHAN
PRIMARY EXAMINER
GROUP 180 *b*